



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

October 16, 2017

Ms. Michelle Ramirez
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, California 95814
Submitted Electronically <https://oehha.ca.gov/comments>

RE: OEHHHA Request for Comments on Possible Listing of n-Hexane

Dear Ms. Ramirez:

The Global Organization for EPA and DHA Omega-3s (GOED) is an international trade association focusing on the fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). GOED works with regulators and scientific groups to ensure consumers have access to high quality EPA and DHA products, as well as accurate information about these valuable nutrients. Thus said, GOED appreciates the opportunity to provide comments in advance of the November 29, 2017 meeting of the Developmental and Reproductive Toxicant Identification Committee (DARTIC) when n-Hexane will be considered for possible listing based on the developmental, male and female reproductive toxicity endpoints. GOED's interest in n-Hexane is due to its use as a solvent that may be used to extract edible oils, including those with EPA and DHA.

GOED supports the comments provided by the Council for Responsible Nutrition (CRN). GOED, like CRN, would like to bring your attention to the Guidelines for Residual Solvents from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) which provides a Permissible Daily Exposure (PDE) of 2.9 mg/day and a concentration limit of 290 ppm.¹ These Guidelines are referenced by the United States Food and Drug Administration (FDA)², Health Canada³ and the European Medicines Agency (EMA).⁴

Thank you once again for the opportunity to provide comments. If you have any questions or require clarification, please do not hesitate to contact me at harry@goedomega3.com or 612-600-6499.

Sincerely,

A handwritten signature in blue ink, appearing to read "Harry B. Rice".

Harry B. Rice, Ph.D.
Vice-President of Regulatory & Scientific Affairs

¹ http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3C/Q3C_R6_Step_4.pdf

² <https://www.fda.gov/downloads/drugs/guidances/ucm073395.pdf>

³ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/impurities-guideline-residual-solvents.html>

⁴ http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/03/WC500104258.pdf